03-01-04

PATENT
674528-2003.1

DAG #15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Abuljadayel
Serial No.	:	09/853,188
Filed	:	May 9, 2001
Examiner	:	Canella
Group Art Unit	:	1642
For	:	**A Device**

745 Fifth Avenue
New York, NY 10151

EXPRESS MAIL

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Date of Deposit: FEBRUARY 27, 2004

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Charles Jackson

(Typed or printed name of person mailing paper or fee)

Charles Jackson

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PETITION TO WITHDRAW HOLDING OF ABANDONMENT UNDER 37 CFR 1.181(a)

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Petition for Withdrawal of the Holding of Abandonment is being filed in response to the Notice of Abandonment rendered on February 19, 2004. The Notice states that Applicant failed to timely file a proper reply to the Office Action mailed on June 3, 2003, and further states that no reply was received.

Applicants wish to respectfully bring to the Commsioner's attention the fact that a response to the June 3, 2003 was indeed timely filed. Attached hereto please find a copy of the response filed on October 3, 2003, the Express Mail receipt, and the postcard receipt returned to us bearing a USPTO date stamp indicating the date of October 3, 2003.

In light of the above, petitioner respectfully requests that the Commissioner withdraw the Holding of Abandonment on this application so that the prosecution of this application be allowed to continue.

It is believed that no fees are required for this Petition. However, in the event that any fees are deemed to be due, the Commissioner is hereby authorized to charge any such fee to Deposit Account No. 50-0320.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By: 

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Mailed Via Exp. Mail # EV287820194S on 10/3/03

Serial No. 09/853,180 File No. 674528-2003.1 By TJK/AMN/SLH
Title in the Matter of the Application of A Device
Applicant(s)/Inventor(s) Abuljadayel
The following due _____ in the U.S. Patent Office, was received in the Patent Office

- ☐ Affidavit
- ☐ Declaration
- ☐ Amendment
- ☐ Preliminary Amendment
- ☐ Amendment After Final Rejection
- ☐ Request for Extension of Time
- ☐ Provisional Patent Application
- ☐ Application for Patent, including ____ Pages Specification ____ Claims ____ Abstract
- ☐ Declaration ☐ Oath ☐ Power
- ☐ Request for Filing Continuation or Divisional Application ____ sheets
- ☐ PCT Request _____ sheets, including
- ☐ Transmittal Letter
- ☐ Request for Continued Exam (RCE)
- ☐ Assignment ☐ Recordation Cover Sheet
- ☐ Amendment Fee Transmittal
- ☐ Claim of Priority
- ☐ Request for Approval of Drawings
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- ☐ Drawing _____ Sheet(s)
- ☐ Information Disclosure Statement
- ☐ PTO Form 1449
- ☐ Issue Fee/Publication Fee Transmittal
- ☐ Appeal Brief (triplicate) ☐ Letter
- ☐ Application for TM Registration Including _____ Specimens
- ☐ Status Request ☐ Notice of Appeal (triplicate)
- ☐ Petition ☐ Response
- ☐ Priority Document
- ☐ Statement of Use
- ☐ Response to Examiner's Statement
- ☐ Search Report
- ☐ Response to Notice to File Missing Parts
- ☒ Response to Office Action with Request for Withdrawal of Restriction Req. and Election of Species and REQUEST FOR EOT

Mailed Via Exp. Mail # EV287820194S on 10/3/03

Serial No. 09/853,180 File No. 674528-2003.1 By TJK/AMN/SLH
Title in the Matter of the Application of A Device
Applicant(s)/Inventor(s) Abuljadayel
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- ☐ Appeal Brief (triplicate) ☐ Letter
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- ☐ Status Request ☐ Notice of Appeal (triplicate)
- ☐ Petition ☐ Response
- ☐ Priority Document
- ☐ Statement of Use
- ☐ Response to Examiner's Statement
- ☐ Search Report
- ☐ Response to Notice to File Missing Parts
- ☒ Response to Office Action with Request for Withdrawal of Restriction Req. and Election of Species and REQUEST FOR EOT

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FROMMER LAWRENCE & HAUG, LLP
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674528-2003.1 (TJK/AMN)

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FROMMER LAWRENCE & HAUG LLP
745 FIFTH AVENUE
NEW YORK, NY 10151

028574

October 3 2003

1-1-210/428

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FROMMER LAWRENCE & HAUG LLP

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IF NOT CORRECT, PLEASE NOTIFY US PROMPTLY. NO RECEIPT DESIRED.

APPLICANT Applicant(s)
SERIAL NO. 09/853,180
TITLE A Device

FIL & H DOCKET NO. 674528-2003.1

- [ ] APPEAL BRIEF
- [ ] APPEAL FEE
- [ ] CERTIFICATE OF CORRECTION
- [ ] DISCLAIMER
- [X] EXTENSION OF TIME
- [ ] FEE FOR ADDED CLAIMS
- [ ] FILING FEE
- [ ] ISSUE FEE
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- [ ] PETITION FEE
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~~674528-2~~ Tristem / Morrison & Foerster	674528-2003.1	TJK / AMN	475 —

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Abuljadayel
Serial No.	:	09/853,180
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RESPONSE TO OFFICE ACTION WITH REQUESTS FOR WITHDRAWAL OF RESTRICTION REQUIREMENT AND ELECTION OF SPECIES AND REQUEST FOR EXTENSION OF TIME

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed June 3, 2003, setting a one-month period for response and requiring restriction and an election of species, Applicants elect with traverse, Group I; Hematopoietic cells from Group A; $CD34^+$ cell surface marker from Group B; and CFC-T cells and T-cells from Group C. Pursuant to 37 C.F.R. §§ 1.136(a) and 1.17(a), a three-month extension of the period for reply, i.e., to up to and including October 3, 2003 is requested. Enclosed is a check in the amount of $475.00 in payment of the fee therefore by a small entity. The Commissioner is hereby authorized to charge any additional fees, or credit any overpayment in fees, to Deposit Account 50-0320.

REMARKS

Reconsideration and withdrawal of the Office Action requiring restriction and an election of species is respectfully requested in view of the remarks herewith.

I. RESPONSE TO RESTRICTION REQUIREMENT

The June 3, 2003 Office Action required restriction from among the following Groups under 35 U.S.C. §121:

Group I: Claims 1-41, drawn to a device for forming or increasing the relative number of undifferentiated cells in a cell population, classified in class 435, subclass 284.1;

Group II: Claims 42-97, drawn to a method for preparing an undifferentiated cell comprising retro-differentiating a more committed cell to a less committed cell, classified in class 435, subclass 377; and,

Group III: Claims 98-100, drawn to a business method comprising supplying a device as claimed in any of claims 1-4 and/or means that are capable of causing a committed cell to retro-differentiate into an undifferentiated cell, classified in class 705, subclass 500.

Applicants elect Group I, with traverse.

The Office Action alleges that the claims of Group I and Group II constitute distinct inventions because they are related as process and apparatus for its practice. Under MPEP §806.05(e) inventions related as process and apparatus for its practice are distinct if it can be shown that either (1) the process as claimed can be practiced by another materially different process or by hand, or (2) the apparatus as claimed can be used to practice another materially different process. The Office Action asserts that in this case the apparatus of Group I can be used for the materially different process of preparing a transformed cell line.

Similarly, the Office Action alleges that the claims of Groups I and III are distinct inventions because they are related as product and process of use. Under MPEP §806.05(h), inventions related as product and process of use may be found to be distinct if it can be shown that either (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. In the instant case, it is alleged that the device of Group I can be used in the method of Group II or of Group III.

Additionally, it is alleged that the claims of Groups II and III are distinct because the methods of Groups II and III differ in the method objectives, method steps and parameters and in the reagents and supplies used.

Further, the Restriction Requirement maintains that " [b]ecause these inventions are distinct ...and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper." Office Action at 3.

It is respectfully requested that the Restriction Requirement be reconsidered and withdrawn, and Groups I, II and III be rejoined such that claims 1-100 are searched and examined together, or at the very least, that Groups I and II be rejoined, such that claims 1-97 are searched and examined together.

The Office Action asserted that the apparatus of Group I can be used to practice the materially different process of preparing a transformed cell line. However, it is respectfully submitted that the preparation of a transformed cell line is not a materially different process, and that, in fact, the use of the apparatus to prepare a transformed cell line falls within the scope of Group I as claimed. Group I relates to a device for increasing the relative number of undifferentiated cells in a population. It is respectfully submitted that undifferentiated cells may comprise transformed cells. The process of transformation in relation to animal cells refers to "the acquisition of cancer like properties" following treatment with an agent (Alberts et al., Molecular Biology of the Cell. Third Edition, 1994). One of the defining features of cancer cells is their ability to proliferate at a higher rate than their neighbors thus giving rise to a tumor. Alberts et al., states that "if a transformed cell is to generate a steadily growing clone of progeny ... the process of differentiation must be deranged so that ... cells retain an ability to carry on dividing indefinitely;" i.e. if a differentiated slowly proliferating or non-proliferating cell is to be transformed, there must be some dedifferentiation to a more primitive proliferative state. Thus, many transformed cells are also undifferentiated cells.

Furthermore, it is respectfully submitted that the claims of Group I and Group II and both classified in class 435, providing further evidence that the search and examination of either group would be likely co-extensive.

In light of the above, it is respectfully submitted that the use of the apparatus of Group I to prepare a transformed cell line does not constitute a materially different process to the claimed use of the apparatus, and thus, the assertion that Group I and Group II are distinct is not proper.

Similarly, the Office Action alleges that the claims of Groups I and III are distinct inventions because they are related as product and process of use, and the device of Group I can be used in the method of Group II or of Group III. It is respectfully submitted that the Claims of Group III are dependent on claims classified in Group I, thereby demonstrating the interrelatedness of Group I and III, such that any search and examination of the Groups would be co-extensive.

Additionally, it is alleged that the claims of Groups II and III are distinct because the methods of Groups II and III differ in the method objectives, method steps and parameters and in the reagents and supplies used. Applicants respectfully disagree. The claims are all directed towards preparation of an undifferentiated cell, or to increasing the relative number of undifferentiated cells in a population of cells, such that any search and examination of Groups II and III are likely to be co-extensive.

In further traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct (MPEP § 803). Second, searching the additional inventions must constitute an undue burden on the examiner if restriction is not required. Under Patent Office examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP § 803) (emphasis added).

The present invention relates to, *inter alia*, methods of preparing undifferentiated cells by retro differentiating more committed cells into less committed cells. It is respectfully asserted that the Office Action, in defining the subject matter of Group I, fails to recognize that the device provides a method of increasing the relative number of cells in a population by retro-differentiating more committed cells into less committed cells. Thus, a search of the claims of Group I would consequently and inextricably encompass a search of the claims included in Groups II and III and vice versa. For example, claims 19-22 in Group I and claims 44-49 in Group II are directed to sources of committed cells, claim 39 in Group I and claim 43 in Group II are directed to use of buffy coat blood samples, claims 23-26 in Group I and claims 50-53 in

Group II are directed to types of undifferentiated cells produced by retro differentiation of committed cells, claims 28-32 in Group I and claims 55-59 in Group II are directed to receptors that mediate capture, recognition or presentation of antigens at the surface of the committed cells, and claims 33-38 in Group I and claims 60-64 in Group 2 are directed to retro differentiation agents. Thus, examination of either Group I or Group II mandates consideration of the patentable elements in the other Group. And, as the claims of Group III are dependent on claims in Group I, the search of Group I would also be interrelated with that of Group III. Indeed, the search and examination of each Group is likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner.

Thus, restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made in the Office Action. All of the preceding, therefore, mitigate against restriction. Accordingly, it is respectfully requested that the restriction requirement be reconsidered and withdrawn.

II. RESPONSE TO ELECTION REQUIREMENT

The June 3, 2003 Office Action further required an election of species at pages 3-4. Hematopoietic cells from Group A, $CD34^+$ cell surface marker from Group B, and CFC-T cells and T-cells from Group C, are hereby elected, with traverse. It is understood that the election of species is only for search and examination purposes, and that it can be expanded to ultimately encompass generic claims such as claim 1 upon determination of allowable subject matter. As will be shown below, species (i) and (ii) of Group C should be rejoined, such that Applicants elect CFC T-cells and T-cells, and CFC B-cells and B-cells.

The Office Action alleges that the application contains claims directed to patentably distinct species of the claimed invention and therefore requires an election of species. However, the requirement of species election is requested without appropriate or due reason. The Examiner states that "Applicant is required under 35 U.S.C. 121 to elect a single disclosed species..." but fails to provide support as to the reason why the members of each species are patentably distinct. Office Action at 4.

In further traverse, a claim reciting all species of Group C has previously been deemed allowable subject matter, as evidenced by claim 16 of U.S. Patent No. 6,090,625.

Further, as the species are not too many in number, it is respectfully submitted that the Examiner must search and examine them together, as MPEP 803.02 specifically provides that members of a *Markush* group must be searched and examined together, if they are not too many in number. Moreover, the examination of the elected species can be extended to the non-elected species.

Therefore, it is respectfully submitted that the election of species requirement should be reconsidered and withdrawn because the species set forth in the claims are sufficiently few in number such that a search and examination thereof can be made without serious burden to the Examiner, and a claim reciting all species of Group C has previously been deemed allowable.

At the very least, it is respectfully requested that the applicants be permitted to elect two species of Group C, namely species (i) CFC T-cells and T-cells, and species (ii) CFC B-cells and B-cells. It is accepted in the art that T-cells and B-cells are closely related, as both are lymphocytes and both function in antigen recognition. Further, it is USPTO practice to recite T-cells and B-cells as members of a single claim, as evidenced by US patents 5,620,689, 5,646,251 and 6,045,788. Therefore, reconsideration and withdrawal of the required election of species is respectfully requested, or, in the alternative, it is respectfully requested that species (i) and (ii) of Group C be rejoined, such that CFC T-cells and T-cells are searched and examined with CFC B-cells and B-cells.

CONCLUSION

Enforcing the present restriction and election of species requirements would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, a shortened patent term may result in any divisional or continuing applications filed).

Further, restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made. Indeed, the search and examination of each Group and species is likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner.

All of the preceding remarks, therefore, mitigate against restriction. In view of the foregoing, reconsideration and withdrawal of the restriction and election of species requirements

and favorable examination of all the claims of Groups I, II and III on the merits are respectfully requested.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By: _____

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GAU 1642 S/N 09853188

Date: 03/02

To: Group Directors/HSAEs

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Subject: Miscellaneous Papers

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OIPE